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10/553,706	08/16/2006	Daniel Plante	1556.0430000/SRL/TAC	5826
26111 7590 6500,00008 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W.			EXAMINER	
			OGUNBIYI, OLUWATOSIN A	
WASHINGTON, DC 20005			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/553,706 PLANTE ET AL. Office Action Summary Examiner Art Unit OLUWATOSIN OGUNBIYI 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 16 August 2006. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-27 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-27 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

U.S. Patent and Trademark Offic PTOL-326 (Rev. 08-06)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date. \_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

Claims 1-52 are pending in the application.

#### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 13-18, drawn to a combination of polynucleotides for amplification and detection of a portion of a Salmonella phoP gene, said portion being less than about 500 nucleotides in length and comprising at least 60 consecutive nucleotides of the sequence set forth in SEQ ID NO:30, said combination comprising: (a) a first polynucleotide primer comprising at least 7 nucleotides of the sequence as set forth in SEQ ID NO:1; (b) a second polynucleotide primer comprising at least 7 nucleotides of a sequence complementary to SEQ ID NO:1; and (c) a polynucleotide probe comprising at least 7 consecutive nucleotides of the sequence as set forth in SEQ ID NO:30, or the complement thereof.

Group II, claim(s) 7-10, drawn to a pair of polynucleotide primers for amplification of a portion of an Salmonella phoP gene, said portion being less than about 500 nucleotides in length and comprising at least 60 consecutive nucleotides of the sequence set forth in SEQ ID NO:30, said pair of polynucleotide primers comprising: (a) a first polynucleotide primer comprising at least 7

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nucleotides of the sequence as set forth in SEQ ID NO:1; and (b) a second polynucleotide primer comprising at least 7 nucleotides of a sequence complementary to SEO ID NO:1..

Group III, claim(s) 11-12, drawn to a method of detecting one or more Salmonella species in a sample, said method comprising: (a) contacting a test sample suspected of containing, or known to contain, a Salmonella target nucleotide sequence with the combination of polynucleotides according to claim 1 under conditions that permit amplification and detection of said target sequence, and (b) detecting any amplified target sequence, wherein detection of an amplified target sequence indicates the presence of one or more Salmonella species in the sample...

Group IV, claim(s) 19-27 drawn to an isolated Salmonella specific polynucleotide having the sequence as set forth in SEQ ID NO:30, or the complement thereof and drawn to a polynucleotide primer of between 7 and 100 nucleotides in length for the amplification of a portion of a Salmonella phoP gene, said polynucleotide comprising at least 7 consecutive nucleotides of the sequence as set forth in SEQ ID NO:30, or the complement thereof and a polynucleotide probe of between 7 and 100 nucleotides in length for detection of Salmonella, said polynucleotide comprising at least 7 consecutive nucleotides of the sequence as set forth in SEQ ID NO:30, or the complement thereof.

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The inventions listed as Groups I and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the groups of inventions I- IV as set forth above are polynucleotides (primers/probes) for the detection of Salmonella Pho P (intended use of the instant polynucleotides). This technical feature is anticipated by the art. New England Biolabs catalog teaches a combination of polynucleotides (random (i.e. all possible sequence combinations) primers 9, 12, 24 or 36) which can be used as primers or primers and probes for the detection of Salmonella PhoP. Said combination of random polynucleotides will necessarily contain polynucleotides comprising at least 7 nucleotides of SEQ ID NO: 1 or any of SEQ ID NO: 16-22 or any of SEQ ID NO: 30 or 32 – 41.

Groups I-IV lack unity, because the technical feature linking the Groups is anticipated by the art and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art. Thus, the inventions listed i.e. Groups I-IV lack unity as a whole.

## Species election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

### Group I

 First and second polynucleotide primers comprising at least 7 nucleotides selected from SEO ID NO: 16-22

Probes comprising at least 7 nucleotides selected from SEO ID NO: 34-40

## Group II

 First and second polynucleotide primers comprising at least 7 nucleotides selected from SEO ID NO: 16-22

## Group IV

• primer - SEQ ID NO: 32,33,35,37,39 and 41.

• probe - SEQ ID NO: 32- 43.

For Group IV please elect a single sequence from both the primer and probe.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following same reasons as set forth above for the inventions. New England teach polynucleotides comprising a sequence of every possible combination (random) of 9 or 12 or 24 or 26 nucleotides.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

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argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

## Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is (571)272-9939. The examiner can normally be reached on M-F 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645